



Certified Medical-grade Manuka honey from LMP

CERTIFIED MANUKA HONEY

Overview

Links Medical Products Inc. (LMP) wound care products containing certified medical-grade Manuka honey display the **CMH** mark verifying those products meet a distinct, independently verified standard. The CMH mark assures customers of a reliable level of purity and chemical composition.

Introduction

To date only limited information defining *medical-grade Manuka honey* has been published in scientific literature. What information is available does not generally provide a comprehensive definition of what constitutes *medical-grade* honey.

LMP's CMH mark represents a reliable, independently verified standard attesting to the purity and chemical composition of Manuka honey used in LMP's wound care products.

Definition of Manuka honey

Authentic Manuka honey is harvested from hives dedicated to bees that gather nectar from the flower of the Manuka bush (*Leptospermum scoparium*) native only to New Zealand. The characteristics of Manuka honey have been well defined in scientific literature, (Molan P.C, University of Waikato) and others¹. Its use in medical applications is also well documented in various reports and studies^{2,3,4,5}.

PA and MGO content of Manuka honey

Most all types of honey contain some level of hydrogen peroxide, the strength of which is sometimes measured and referred to as peroxide activity (PA). However, the peroxide activity of all honey is short-lived.

Manuka honey contains hydrogen peroxide, but what makes it different from other honey is its content of non-peroxide substances not found in other types of honey - specifically methylglyoxal (MGO) and dihydroxyacetone (DHA).

While Manuka honey may exhibit some PA, it is the non-peroxide activity (NPA) associated with MGO that defines the unique chemical composition of Manuka honey.

Page 2. CMH (cont.)

About MGO and DHA

Recently, researchers^{6,7,8,9} have firmly established Manuka honey from the *Leptospermum scoparium* bush contains high levels of the compound MGO.

MGO and its precursor DHA have been proven to be compounds which most significantly differentiate Manuka honey's unique properties from those of other types of honey.

Definition of Certified Medical-grade Manuka honey (CMH)

The CMH mark provides assurance to healthcare professionals that LMP products employed in wound care applications have met stringent and consistent requirements for purity and composition.

To define the standard for medical-grade Manuka honey, LMP established a distinct set of process methods and controls including compliance to well established GMP standards.

Certification Testing

Before processing by LMP, the Manuka honey is subjected to extensive testing by an independent UK based laboratory, conforming to ISO/IED 17025 standards.

Note: In major countries around the world, ISO/IED 17025 is the standard laboratories must meet and hold accreditation in order to be recognized as technically competent. In nearly all cases, suppliers and regulatory authorities will not accept test results from a non-accredited lab.

The specific tests used for LMP's medical-grade Manuka honey verify and certify purity and composition. The basis of these tests were substantiated through established data and protocols cited by the New Zealand government related to the definition and protection of Manuka honey. The tests were also informed via collaboration and communication from an independent New Zealand laboratory performing work associated with the New Zealand Manuka honey industry.

The tests used to assure wound specialists of CMH marked medical-grade Manuka honey include those required to guarantee authenticity. Tests include the measurement of methylglyoxal (MGO) and dihydroxyacetone (DHA) a precursor to MGO content.

The level of NPA antibacterial property of the honey is measured and compared against the standard phenol bioassay.

Page 3. CMH (cont.)

Specific LMP process protocols include

Product Storage, processing, sterilization and laboratory confirmation testing are all part of LMP's proprietary process for creating "medical-grade" manuka honey.

Honey storage

The honey is stored under tightly controlled conditions that meet current Good Manufacturing Practices (GMP) standards for receiving, storage and record keeping. This process verifies only New Zealand Manuka is received.

Filtration

Filtration is used to remove any extraneous particles, such as bee body parts.

Homogenization

The homogenization process assures uniformity of raw honey and reduces the potential for crystallization.

Sterilization

Following production, the finished products are sterilized by gamma ray methods conforming to ISO guidelines for medical devices.

Note: LMP's wound care dressings also carry the authorized CE mark necessary for marketing in the European Economic Area (EEA) and the European Free Trade Association (EFTA) countries. Sold worldwide, the products have also been cleared for marketing through the United States Food and Drug Administration (FDA).

Conclusion

The CMH mark on LMP wound care dressings assures healthcare professionals the products bearing the mark do, in fact, contain authentic medical-grade Manuka honey and have been tested and certified as meeting the high standards required for wound care application.

References attached

Page 4. CMH (cont.)

References

1. Molan, P. (2013). The use of manuka honey to promote wound healing. L.O.G.I.C (Linking Opportunities Generating Inter-Professional Collaboration): The Official Journal of The New Zealand College of Primary Health Care Nurses, NZNO, March 2013, 23-25.
2. Lu J, Carter DA, Turnbull L, Rosendale D, Hedderley D, et al. (2013) The Effect of New Zealand Kanuka, Manuka and Clover Honeys on Bacterial Growth Dynamics and Cellular Morphology Varies According to the Species. PLoS ONE 2013 13; 8(2):e55898.
3. Seckam A, Cooper R. (2013) Understanding how honey impacts on wounds: an update on recent research findings. Wounds International Vol 4 | Issue 1 |
4. Eric N Hammond EN, Eric S Donkor, ES (2013) Antibacterial effect of Manuka honey on Clostridium difficile. BMC Research Notes 2013, 6:188
5. Gethin GT1, Cowman S, Conroy RM. The impact of Manuka honey dressings on the surface pH of chronic wounds. Int. Wound J. 2008 Jun;5(2):185-94.
6. (Leptospermum scoparium) honey. Carbohydr Res. 2012 Nov 1;361:7-11. doi: 10.1016/j.carres.2012.07.025. Epub 2012 Aug 8. Atrott J1, Haberlau S, Henle T.
7. Identification and quantification of methylglyoxal as the dominant antibacterial constituent of Manuka (Leptospermum scoparium) honeys from New Zealand. Mol Nutr Food Res 2008 Apr;52(4):483-9 Elvira Mavric, Silvia Wittmann, Gerold Barth, Thomas Henle
8. The origin of methylglyoxal in New Zealand manuka (Leptospermum scoparium) honey. Carbohydr Res. 2009 May 26;344(8):1050-3. doi: 10.1016/j.carres.2009.03.020. Epub 2009 Mar 21. Adams CJ1, Manley-Harris M, Molan PC
- 9 .Studies on the formation of methylglyoxal from dihydroxyacetone in Manuka (Leptospermum scoparium) honey. Carbohydr Res 2012 Nov 8;361:7-11. Epub 2012 Aug 8. Julia Atrott, Steffi Haberlau, Thomas Henle